IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant: Dan ALESI et al.

Serial No: 09/920,860

Filed: August 3, 2001

For: NEEDLE SAFETY DEVICE WITH TORTUOUS PATH

Appeal No.

APPELLANTS' SUPPLEMENTAL BRIEF ON EX PARTE APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a brief for appealing the final rejecting of pending claims 1-3, 5-12, 14-20 and 22-26 the above-identified application.

TABLE OF CONTENTS

This is a Supplemental Appeal Brief accompanying the Request for Reinstatement of the Appeal in light of the reopening of the prosecution of the instant application by the examiner per the Office Action dated March 16, 2004 in response to the submission of the Appeal Brief dated September 22, 2003.

For the convenience of the Board, the contents under the headings of "Real Party in Interest", "Related Appeals and Interferences" and "Summary of the Invention" of the Appeal Brief are reproduced in this Supplemental Appeal Brief. The contents under "Status of Claims" and "Status of Amendments" have been updated to reflect the Office Action that reopened the prosecution of this case. The contents under the remaining headings are new, as a new reference has been relied upon by the examiner.

REAL PARTY IN INTEREST

The real party in interest for this appeal is Portex, Inc.[1] to whom the inventors assigned the invention per an assignment recorded on August 3, 2001 with the Assignment Branch of the U.S. Patent and Trademark Office.

RELATED APPEALS AND INTERFERENCES

As far as is known, it is believed that there are no appeals or interferences that would directly affect or be directly affected by or have a bearing on the Board's decision on the pending appeal.

STATUS OF CLAIMS

Claims 1-26 were presented for prosecution with the filing of the instant application on August 3, 2001. In response to a Restriction Requirement dated September 6, 2002, appellants elected for prosecution claims 1-3, 5-12, 14-20 and 22-26. In response to an Office Action dated November 13, 2002, an Amendment was filed on February 12, 2003 in which claim 6 was amended to overcome an

[1] The name of Portex, Inc. has been changed to Smiths Medical ASD, Inc.

objection by the examiner. An Office Action dated May 6, 2003 final rejected all of the pending claims.

An Appeal Brief was filed on September 22, 2003 appealing the final rejection of all of the pending claims by the Office Action dated May 6, 2003. An Office Action dated March 16, 2004 reopened the prosecution. This Supplemental Appeal Brief is filed in accompaniment of a Request to Reinstate the Appeal.

The claims at issue in this case and herein on appeal accordingly are claims 1-3, 5-12, 14-20 and 22-26, as reproduced in Appendix A herein. For the convenience of the Board, withdrawn claims 4, 13 and 21 are included and noted as such in the claims of Appendix A.

STATUS OF AMENDMENTS

There was no Amendment filed subsequent to the final rejection Office Action dated May 6, 2003. Nor was there any amendment to the claims in response to the Office Action dated March 16, 2004 reopening prosecution of this case.

SUMMARY OF THE INVENTION

The instant invention, as set forth in claim 1, relates to an apparatus that comprises a holder (2) having one and other ends (4, 6), with the one end having an extension (8) and a sleeve (14) extending from the extension. [Page 6, lines 15-16; Fig. 3][2] A double ended needle (18) having a base (24) is mated to the extension (8) of the holder . One end of the needle (20) extends away from the holder while the other end of the needle extends into the holder. The base (24) of the needle is substantially positioned within the sleeve (14). [Page 6, lines 6-9; Figs. 5, 6, 8] A collar (10) having a housing (12) pivotally extending therefrom is mounted about the extension (8). [Page 9, lines 3-7; Figs. 2, 5-8] A sheath (28) that has an open end is matingly fitted to the sleeve (14) to establish an environment sealed against

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[2] The designations of the different elements recited in the claims are in parentheticals while the pages of the disclosure that provide support are bracketed.

bacteria intrusion for the one end of the needle (20). [Page 7, lines 10-20; Fig. 6] The instant invention therefore is related to the establishment of an environment for maintaining the sterility of a needle that is to be used on a patient, by providing a sheath that mates to a sleeve, which extends from an extension, or the neck, of the holder to thereby establish a sealed environment for the needle.

Additional variants of the instant invention are set forth in independent claims 10 and 18. Independent claim 10 relates to a blood drawing device which, due to the interaction of the sheath (28) fitted to the sleeve (14) that extends from the neck (8) of the holder (2), as well as the mating of the double-ended needle by means of its base (24) into the neck (8) of the holder, establishes an environment impervious to bacteria intrusion for the space inside the sheath that encloses the needle (20) that is to be used with a patient. The same disclosures as noted above with respect to claim 1 provide support for claim 10.

Independent claim 18 relates to a needle device that, similarly, by means of the interrelationship between the sheath (28) that covers needle (2), the base or needle hub (24) that is mated to the neck (8) of the body holder (2) and the sleeve (14) that extends from the neck, is able to establish an environment impervious to bacteria intrusion inside the space of the sheath (28) where the needle (20) resides.

Other aspects of the invention include the recitation of the interaction between the different surfaces (28s, 14s) of the sheath (28) and sleeve (14) that together effect a tortuous path (30) to seal the inside of the sheath against potential bacteria intrusion. [Page 7, lines 12-20; Fig. 6] This aspect of the invention is set forth in dependent claims 2, 11 and 19.

Claims 3, 12 and 20 each define sleeve (14) to be integrally extending from the extension or the neck (8) of the holder. [Page 6, lines 15-16; Figs. 2 and 4-6]

Claims 5, 14 and 22 each define housing (12) to have an integral locking means (46) for grasping the needle (20) when the housing is pivoted to cover the

needle after the sheath (28) has been removed from the sleeve. [Page 9, lines 3-8; Fig. 5]

The coacting locking portions provided at the collar (10) or sleeve (14), and the housing (12) is defined in claims 6, 15 and 23.

Claims 7, 16 and 26 each define the placing of a cover (16) at the end (6) of the holder (2) to provide a sterile environment for the inside 19 of the holder. [Page 6, lines 17-21; Figs. 4, 5]

In addition, claim 16, as well as claims 9 and 24 individually, each define either means or a tamper seal (40) provided on the sheath (28) and the sleeve (14) to provide evidence that there is a sealed environment (34) for the needle (20). [Page 8, lines 13-17; Fig. 2]

ISSUES

In the Office Action dated March 16, 2004, the examiner has rejected claims 1, 3, 5-8, 10-12, 14-15, 17-18, 20, 22-23 and 25-26 under 35 U.S.C. 102(b) as being anticipated by Landis (USP 5,490,841). Claims 1-3, 5-8, 10-12, 14-15, 17-20 and 25-26 were rejected under 35 U.S.C. 102(a) as being unpatentable over Hollister (USP 5,277,311) in view of Landis. Claims 9, 16 and 24 were rejected under 35 U.S.C. 103(a) as being obvious over either the combination of Landis and Imbert (USP 6,027,482) or Hollister, Landis and Imbert.

In view of the examiner's rejections, the issues presented herein on appeal are the following:

1. Is the 35 U.S.C. 102(b) rejection of the above noted claims in view of Landis justified?

2. Is the 35 U.S.C. 103(a) rejection of the above-noted claims in view of the combination of Hollister and Landis sustainable?

3. Are the different combinations of Landis/Imbert and Hollister/Landis/Imbert for rejecting the above-noted claims sustainable?

GROUPING OF CLAIMS

The being appealed claims, as discussed above in the Summary of the Invention section, are divided into three sets, namely claims 1-9, 10-17 and 18-26. Dependent claims 2-3 and 5-9 each depend from claim 1, dependent claims 11-12 and 14-17 each depend from claim 10, and dependent claims 19-20 and 22-26 each depend from claim 18. In the hereinbelow Argument section, in addition to independent claims 1, 10 and 18, appellants will also argue separately the patentability of claims 2-3, 6-7, 9, 11-12, 15-16, 19-20, 23-24 and 26. Thus, appellants respectfully submit that all of the claims do not stand or fall together, but rather that the patentability of each of the above noted claims to which discussion is to be had hereinbelow should be considered independently.

ARGUMENT

Issue 1

Is each of claims 1-3, 5-8, 10-12, 14-15, 17-18, 20, 22-23 and 25-26 anticipated by Landis (USP 5,490,841) under 35 U.S.C. 102(b)?

"In order to prove that a claim is anticipated under 35 U.S.C. 102(b), defendants must present clear and convincing evidence that a single prior art reference discloses, either expressly or inherently, each limitation of the claim." In re Cruciferous Sprout litigation, 301 F.3d 1343, 1348 (Fed. Cir. 2002). In In re Robertson, the CAFC further held: "Anticipation under 35 U.S.C. 102(e) requires that `each and every element as set forth in the claim is found either expressly or inherently described, in a single prior art reference`". 169 F.3d 743, 746 (Fed. Cir. 1999)

Independent claim 1 recites a holder that has an extension at its one end, and a sleeve extending from the extension. Moreover, the apparatus of claim 1 includes

a double ended needle having a base that is substantially positioned within the sleeve. Furthermore, the apparatus of claim 1 includes a sheath that matingly fits to the sleeve to establish an environment which seals the needle of the double ended needle that extends away from the holder from bacteria intrusion.

Independent claim 10 defines a blood drawing device that has a holder which has a neck and to which a sleeve extends. The base of a double ended needle is connected to the neck of the holder. A sheath is fitted to the sleeve in such a way that the sleeve, the base and the sheath in combination establish an environment for the space inside the sheath that encloses the needle impervious to bacteria intrusion.

Independent claim 18 likewise defines a needle device that has a body having a neck to which a needle is connected by means of a base. The needle device of claim 18 has a sleeve that extends from the neck to enclose the base, and a sheath that fits to the sleeve such that the sleeve, the base and the open end of the sheath that mates to the sleeve in combination establish a bacteria free space inside the sheath where the needle extends from the base.

Landis discloses a luer fitting 32 that has attached thereto a housing 12, by way of a hinge 14. Luer fitting 32 has a female receptor 32B to which a needle hub or needle base 32 of a needle 40 could be mated. The luer fitting 32 further has a male fitting 32A that allows the luer fitting 32 to be mated to a female luer 34A of a syringe 34. A needle sheath 42 covers needle 40 prior to use. The needle base 36, the needle 40 extending from it, and the needle sheath 42 that covers the needle 40 prior to use are together referred to as the needle assembly 38. See Fig. 4 and column 6, lines 10-66 for the discussion of the various components of the Landis device as shown in Fig. 4.

In the Office Action, the examiner states: "Landis discloses an apparatus (Fig. 4) comprising a holder having one and other ends, said one end having an extension (36) and a sleeve extending from said extension, a doubled-ended needle (column

7, lines 29-44), a collar, a housing pivotally extending from said collar (12), and a sheath (42)." [Page 2 of Office Action] In support of her assertion, the examiner reproduces a portion of the Fig. 4 drawing on page 2 of the March 16, 2004 Office Action, with fitting 32 being identified as "collar", and needle sheath 42 or a portion of needle base 36 designated as "sleeve".

Appellants respectfully submit that there is no "holder" disclosed by Landis. The closest thing that arguably could be considered a holder in Landis is syringe 34. Yet syringe 34 does not have an extension that has "a sleeve extending from the extension". Yet, by designating either a portion of needle base 36 or needle sheath 42 as the "sleeve", it would appear that the examiner is asserting that Landis needle base 36 (or needle hub) is a holder. But the claims, for example claim 1, requires "a double ended needle having a base mated to said extension of said one end of said holder, one end of said needle extends away from said holder while other end of said needle extends into said holder, said base of said needle being substantially positioned within said sleeve". Thus, insofar as the needle hub 36 already has needle 40 extending therefrom, and that needle 40 is integrally molded to needle hub 36, there could not possibly be any "double ended needle" being mated to the needle base 36 of the Landis device. This is made clear in column 7, lines 29-44 of Landis, referenced by the examiner, which states: "By way of example only, luer fitting 32 could be adapted to receive a different size or type of needle, such as a double-ended needle typically used in blood sampling procedures." In other words, what Landis discloses is that the conventional single ended needle assembly such as 38 shown in Landis, could be replaced with a double ended needle that is to be mated to luer fitting 32. Whether or not that would work with the Fig. 4 embodiment shown by Landis is another question. But the thing to consider is that a double-ended needle would have its own needle base, or needle hub, which certainly could not be considered as a holder. Thus, no matter how one tries to interpret Landis, there nonetheless could not be any "holder" as claimed in the instant invention that is disclosed in Landis.

In her above-quoted statement, the examiner states that "said one end having an extension (36) and a sleeve extending from said extension".

Here, it is obvious that the examiner refers to needle base 36 as an extension and the portion of needle base to which needle 40 is molded as a sleeve. As can clearly be shown and as is well known in the industry, the portion of the needle hub to which a needle is attached is not and could not be a "sleeve", which by common definition is "a tubular part (as a hallow axle or a bushing) designed to fit over another part" (Webster's Ninth New Collegiate Dictionary, 1984). Thus, the solid portion of needle base 32 to which needle 40 is attached could not therefore possibly be considered as a sleeve.

On the other hand, the examiner may well be referring to needle sheath 42 as the claimed "sleeve". If that were the case, then what exactly is needle sheath 42? Is it a sleeve or is it a needle sheath? In any event, the exemplar claim 1 as noted above recites "a sheath having an open end, said open end having a circumference that enables the sheath to matingly fit to said sleeve to establish an environment sealed against bacteria intrusion for said one end of said needle". Thus, the claim at issue requires that there be a "sheath" that interacts with a "sleeve". In contrast, at best, Landis discloses a needle sheath 42. There simply is no sleeve disclosed in Landis.

Appellants further respectfully submit that the luer fitting 32 of the Landis device could not be construed as the claimed "collar", as luer fitting 32 of the Landis device is essentially an adapter that interposes between a conventional syringe and a conventional needle assembly, in order to provide a housing 12 that integrally attaches to luer fitting by hinge 14. Thus, luer fitting 32 could not possibly be the claimed "collar" that mounts about the extension, particularly since the examiner has indicated that needle base 32 of the Landis device is the extension.

In sum, Landis does not disclose a holder, a sleeve extending from the extension, a double ended needle mated to the extension with the base of the

needle being substantially positioned within the sleeve, a collar mounted about the extension, or a sheath that has an open end having a circumference that enables the sheath to matingly fit to the sleeve to establish an environment sealed against bacteria intrusion for the needle.

In light of the elements that are missing in Landis vis-a-vis those claimed in the at issue claims, appellants respectfully submits that each of independent claims 1, 10 and 18 is not anticipated by Landis.

Appellants further respectfully submit that Landis also fails to disclose any tortuous path as set forth in claims 2, 11 and 19. Nor does Landis disclose any interaction between the respective surfaces of the sheath and the sleeve [claim 2], or the sheath, the base and the sleeve [claims 11 and 19] for effecting the tortuous path. At best, Landis shows needle sheath 42 fitting over the portion of needle hub 36 to which needle 40 extends. Thus, even when needle hub 36 is mated to the female receptor 32B of luer fitting 32, needle hub 34 is exposed. Thus, there could not be any tortuous path established in the Landis device when needle hub 36 is mated to luer fitting 32. Accordingly, claims 2, 11 and 19 each are not anticipated by Landis.

Claims 3, 12 and 20 each recite the sleeve being integrally extending from the extension [claim 3] or the neck [claims 12 and 20] of the holder. As identified by the examiner in the Office Action, the "sleeve" is actually extending from the needle hub. Claims 3, 12 and 20 therefore each are likewise not anticipated by Landis. Landis does not disclose any coacting locking portions at the housing/collar as disclosed in claims 6, 15 and 23. Thus, those claims are not anticipated by Landis.

Landis also fails to disclose any cover that seals the open end of the vacuum tube holder (which is not disclosed to begin with in Landis) to provide a sterile environment for the space (19) within the vacuum tube holder, as defined in claim 7, 16 and 26.

Landis further fails to disclose any collar rotatable about the extension. This is clear insofar as the asserted "collar" is actually a luer fitting that, once mated to syringe 34, will stay fixed and not rotatable about the syringe. Nor is there any disclosure in Landis that his housing 12 is rotatable relative to needle 42. Thus, claims 8, 17 and 25 each are not anticipated by Landis.

In sum, appellants respectfully submit that each of claims 1, 3, 6-8, 10, 12, 15, 17-18, 20, 23 and 25-26 is not anticipated by Landis.

Issue 2

Are claims 1-3, 5-8, 10-12, 14-15, 17-20, 22-23 and 25-26 obvious over the combination of Landis and Hollister (5,277,311).

Hollister discloses a vacuum tube holder 2 that has mounted to its neck or receptacle end 6 a collar 18. A housing 20 is connected to the collar by a living hinge 24. A double ended needle assembly 30 is threadingly mated to receptacle end 6 of holder 2. See Fig. 1. There is therefore no sleeve extending from the neck (or extension) disclosed in Hollister.

In the Office Action, the examiner asserts that "Hollister discloses an apparatus comprising a holder (2) having an extension and a sleeve integrally extending from said extension". Yet the examiner fails to point out where in Hollister is there any disclosure of a "sleeve". Simply saying something does not make it true.

The examiner further went on to state "Hollister discloses all of the claimed limitations except a sheath having an open end having a circumference that enables the sheath to matingly fit to said sleeve. Landis does disclose a sheath/cap/needle cover (42) having an open end. It would have been obvious to one of ordinary skill in the art to use the teachings of Landis to modify the invention of Hollister and put a sheath/cap/needle cover on the needle in order to keep the needle sterile and prevent it from exposure to contaminants."

Even if needle 28 of the needle assembly 30 of the Hollister device were to be covered with a needle sheath such as 42 shown in Landis, the fact remains that that sheath does not mate to any sleeve in holder 22 of Hollister, as only the threads 40 of the needle assembly 30 is threaded into the threaded aperture of receptacle end 6. In other words, however a needle sheath covers needle 28 of the needle assembly 30 has no bearing on the mating of needle assembly 30 to holder 2 of the Hollister device. Putting it yet differently, even assuming that a needle sheath does cover needle 28 in the Hollister device as shown in Fig. 1, that sheath would not have any interaction with any part of receptacle end 6 of holder 2, as there simply is no sleeve present in the Hollister device shown in Fig. 1. The fact that the needle, and the needle hub to which the needle attaches, remain outside of receptacle end 6 is shown more clearly in the perspective view of Fig. 4 of Hollister. A needle sheath fitted over needle 28 of the Hollister device could not therefore matingly fit to a non-existent sleeve. Thus, even were Hollister to be combined with Landis as suggested in the Office Action, the fact remains that there is no sleeve and therefore there could not be any interaction between a needle sheath and a non-existent sleeve. The combination of Hollister and Landis therefore could not render as obvious the invention as set forth in independent claims 1, 10 and 18.

Given that there is no sleeve disclosed in Hollister, there could not be any interaction between the surfaces of the sheath and the sleeve as recited in claims 2, 11 and 19.

Given that there is no sleeve disclosed in Hollister, there could not be any sleeve integrally extending from the extension as recited in claims 3, 12 and 20 for the Hollister/Landis combination.

There also are no coacting locking portions disclosed in either Landis or Hollister. That being the case, claim 6, 15 and 23 each could not be obvious over the Hollister/Landis combination.

Hollister and Landis each also fail to disclose any cover that seals the other end of the holder. Thus, claims 7 and 26 each could not be obvious over the Hollister/Landis combination.

In sum, Appellants respectfully submit that claims 1-3, 6-7, 10-12, 15, 18-20, 23 and 26 each are not obvious over the Hollister/Landis combination.

Issue 3

Claims 9, 16 and 24 were rejected under Landis in combination with Imbert (USP 6,027,482) or the combination of Hollister/Landis and further in view of Imbert.

Claims 9, 16 and 24 depend from independent claims 1, 10 and 18, respectively, and each recite means [claim 9] or a tamper seal [claims 16 and 24] on the sheath and the sleeve to provide evidence that the sealed environment of the needle has been compromised. Insofar as neither Landis nor Hollister discloses any sleeve, that alone renders claims 9, 16 and 24 not obvious over the combination of Landis/Imbert or the combination of Hollister/Landis/Imbert.

In summation, Appellants respectfully submit that the prior art rejections of the at issue claims, as discussed above, each are not sustainable. Accordingly, Appellants respectfully request that the examiner's rejections of pending claims 1-3, 5-12, 14-20 and 22-26 be reversed.

Respectfully submitted,

Louis Woo, Reg. No. 31,730
Law Offices of Louis Woo
717 N. Fayette Street
Alexandria, VA 22314
Phone: (703) 299-4090

Date: June 15 2004

APPENDIX A

1. (original) Apparatus, comprising:

a holder having one and other ends, said one end having an extension and a sleeve extending from said extension;

a double ended needle having a base mated to said extension of said one end of said holder, one end of said needle extends away from said holder while other end of said needle extends into said holder, said base of said needle being substantially positioned within said sleeve;

a collar mounted about said extension;

a housing pivotally extending from said collar;

a sheath having an open end, said open end having a circumference that enables the sheath to matingly fit to said sleeve to establish an environment sealed against bacteria intrusion for said one end of said needle.

2. (original) Apparatus of claim 1, wherein the surface of the open end of said sheath and the surface of said sleeve that come into contact with each other effect a tortuous path to seal the inside of said sheath against potential bacteria intrusion.

3. (original) Apparatus of claim 1, wherein said sleeve integrally extends from said extension.

4. (withdrawn) Apparatus of claim 1, wherein said sleeve comprises a semi-closed end having an opening substantially matching the opening of said extension and through which the portion of said base of said needle that mates to said extension passes, said sleeve sealingly fitting onto said extension when said base of said needle is mated to said extension.

5. (original) Apparatus of claim 1, wherein said housing further comprises an integral locking means for grasping said one end of said needle when said housing is pivoted to cover said one end of said needle after said sheath has been removed from said sleeve.

6. (previously presented) Apparatus of claim 1, wherein said housing comprises at least one locking portion that coacts with at least another locking portion at said collar or said sleeve to fixedly retain said housing along a longitudinal axis of said holder to cover said one end of said needle after said sheath has been removed from said sleeve.

7. (original) Apparatus of claim 1, further comprising:

a cover sealing said other end of said holder to provide a sterile environment for the inside of said holder.

8. (original) Apparatus of claim 1, wherein said collar is rotatable about said extension so that said housing is rotatable relative to said one end of said needle.

9. (original) Apparatus of claim 1, further comprising:

means on said sheath and said sleeve to provide evidence that the sealed environment of said one end of said needle has been compromised.

10. (original) Blood drawing device comprising a holder having one and other ends, said one end having a neck to which a sleeve extends, a double ended needle connected to said neck via a base so that one end of said needle extends away from said holder and other end of said needle extends within said holder, a collar having a housing pivotally connected thereto mounted about said neck, a sheath having an open end matingly fitted to said sleeve, wherein said base is positioned substantially within said sleeve and said open end of said sheath is fitted to said sleeve in such a way that said sleeve, said base and said open end of said sheath in combination establish an environment impervious to bacteria intrusion for the space inside said sheath that encloses said one end of said needle.

11. (original) Device of claim 10, wherein the surfaces of said sheath that come into contact with the respective surfaces of said base and said sleeve effect a tortuous path to seal said space inside said sheath that encloses said one end of said needle.

12. (original) Device of claim 10, wherein said sleeve integrally extends from said neck.

13. (withdrawn) Device of claim 10, wherein said sleeve comprises a semi-closed end having an opening substantially matching the opening of said neck sealingly fitted onto said neck when said needle is connected to said neck.

14. (original) Device of claim 10, wherein said housing further comprises an integral locking means for grasping said needle when said housing is pivoted to cover said needle after said sheath has been removed from said sleeve.

15. (original) Device of claim 10, wherein said housing comprises at least one locking portion that coacts with at least an other locking portion at said collar or said sleeve to fixedly retain said housing along a longitudinal axis of said holder to cover said needle after said sheath has been removed from said sleeve.

16. (original) Device of claim 10, further comprising:

a cover sealing said other end of said holder to provide a sterile environment for the inside of said holder; and

a tamper seal on said sheath and sleeve that, when broken, provides evidence that the sealed environment of said needle has been compromised.

17. (original) Device of claim 10, wherein said collar is rotatable about said neck and said housing is rotatable relative to said needle.

18. (original) A needle device comprising a body having a neck to which a needle is connected via a base, a sleeve extending from said neck to enclose said base, a collar having a housing for covering said needle pivotally connected thereto mounted about said neck, a sheath having an open end matingly fitted to said sleeve, said sleeve, said base and said open end of said sheath that mates to said sleeve in combination establish an environment impervious to bacteria intrusion for the space inside said sheath that encloses said needle.

19. (original) Device of claim 18, wherein the surfaces of said sheath that come into contact with the respective surfaces of said base and said sleeve effect a tortuous path to seal said space inside said sheath that encloses said one end of said needle.

20. (original) Device of claim 18, wherein said sleeve integrally extends from said neck.

21. (withdrawn) Device of claim 18, wherein said sleeve comprises a semi-closed end having an opening substantially matching the opening of said neck sealingly fitted onto said neck when said needle is connected to said neck.

22. (original) Device of claim 18, wherein said housing further comprises an integral locking means for grasping said needle when said housing is pivoted to cover said needle after said sheath has been removed from said sleeve.

23. (original) Device of claim 18, wherein said housing comprises at least one locking portion that coacts with at least an other locking portion at said collar or said sleeve to fixedly retain said housing along a longitudinal axis of said holder to cover said needle after said sheath has been removed from said sleeve.

24. (original) Device of claim 18, further comprising:

a tamper seal on said sheath and sleeve that, when broken, provides evidence that the sealed environment of said needle has been compromised.

25. (original) Device of claim 18, wherein said collar is rotatable about said neck and said housing is rotatable relative to said needle.

26. (original) Device of claim 18, wherein said body comprises a Vacutainer holder having one end wherefrom said neck extends and an other open end sealed with a cover to provide a sterile environment within said holder.

CITATIONS